PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of	)	
CERTAIN TADALAFIL OR ANY SALT OR SOLVATE THEREOF AND PRODUCTS CONTAINING SAME	)	**Inv. No. 337-TA-539**

COMMISSION OPINION

INTRODUCTION

This investigation is before the Commission for final disposition, including determinations on remedy, the public interest, and bonding.

PROCEDURAL BACKGROUND

The Commission instituted this investigation based on a complaint filed by Lilly ICOS LLC ("Lilly") of Wilmington, Delaware, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337. 70 *Fed. Reg.* 25601 (May 13, 2005). The complaint, as supplemented, alleged violations of section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain tadalafil or any salt or solvate thereof, and products containing same by reason of infringement of claims 1-4, 6-8, 12, and 13 of U.S. Patent No. 5,859,006. Tadalafil is a pharmaceutical composition used for the treatment of erectile dysfunction. Lilly markets its tadalafil composition under the trade name Cialis®.

The complaint and notice of investigation named ten respondents. On September 12,

2005, the Commission issued a notice indicating that it had determined not to review an initial determination ("ID") (Order No. 5) finding four respondents, *viz*., Santovittorio Holdings Ltd. d/b/a Inhousepharmacy.co.uk of El Dorado, Panama; Stop4Rx of Port-au-Prince, Haiti; Rx Mex-Com, S.A. de C.V. of Colonia Las Brisas, Mexico; and www.Nudewfds.info of New Orleans, Louisiana in default. The presiding administrative law judge ("ALJ")also found that respondent Express Generic had not been properly served with the complaint. Order No. 5 was not reviewed by the Commission.

On November 17, 2005, the Commission issued a notice that it had determined not to review an ID (Order No. 9) finding an additional five of the originally named respondents in default. The additional five respondents were Budget Medicines Pty Ltd., of Sydney, Australia; Generic Cialis Pharmacy of Managua, Nicaragua; Cutprice Pills of Scottsdale, Arizona; Allpills.us of Beverly Hills, California; and Pharmacy4u.us of New York, New York.

On October 28, 2005, Lilly filed a motion for summary determination on the issues of domestic industry and violation of section 337 by reason of patent infringement with respect to the nine respondents that were found in default. On November 14, 2005, the Commission investigative attorney (“IA”) filed a response in support of the motion.

On December 6, 2005, the ALJ issued an ID (Order No. 10) granting Lilly’s motion for a summary determination of a violation of section 337 with respect to the nine defaulting respondents. At the same time, the ALJ recommended issuance of a general exclusion order under section 337(g)(2), 19 U.S.C. § 1337(g)(2). The ALJ also recommended that the bond permitting importation during the period of Presidential review be set at 100 percent of the value

of the infringing imported products. No party petitioned for review of the ID, and the Commission declined to review it. The ID finding a violation of section 337 became the Commission's final determination on January 4, 2006. 71 *Fed. Reg*. 1452 (Jan. 9, 2006).

Pursuant to the Commission's notice, Lilly and the IA submitted main briefs on the issues of remedy, the public interest, and bonding on January 17, 2006, with draft general exclusion orders attached. The IA filed a reply submission on January 24, 2006. Lilly filed a motion to file a surreply with its surreply attached on February 9, 2006.

DISCUSSION

A. Remedy

1. The RD

The ALJ found that the issuance of a general exclusion order in this investigation case is authorized by section 337(g)(2), which provides:

> In addition to the authority of the Commission to issue a general exclusion order from entry of articles when a respondent appears to contest an investigation concerning a violation of the provisions of this section, a general exclusion from entry of articles, regardless of the source or importer of the articles, may be issued if –
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> (A) no person appears to contest an investigation concerning a violation of the provisions of this section,
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> (B) such a violation is established by substantial, reliable, and probative evidence, and
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> (C) the requirements of subsection (d)(2) are met.

19 U.S.C. §1337(g)(2)(A)-(C). Section 337(d)(2), referred to in section 337(g)(2)(C), provides:

> The authority of the Commission to order an exclusion from entry of articles shall be limited to persons determined by the Commission to be violating this section unless the Commission determines that-
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> (A) a general exclusion from entry of articles is necessary to prevent circumvention of an exclusion order limited to products of named persons; or
>
> (B) there is a pattern of violation of this section and it is difficult to identify the source of the infringing product.

19 U.S.C. §1337(d)(2)(A)-(B)

The ALJ determined that section 337(g)(2) authorized the issuance of a general exclusion order in this investigation because no party appeared to contest the investigation. He noted that of the nine entities who were served with the complaint and notice of investigation, nine were found in default. [1] The tenth entity, Express Generic, was not properly served and, therefore, not found in default.[2] Regarding the nine entities who were properly served, the ALJ found that Lilly has "amply established by 'substantial, reliable, and probative evidence' that a violation has occurred and continues to occur."[3] The Commission determined not to review the ID's finding of violation, thereby allowing it to become the Commission's final determination. 71 *Fed. Reg.* 1452 (Jan. 9, 2006).

Turning to his recommendation on remedy, the ALJ further found that the conditions for

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[1] Santovittorio Holdings Ltd d/b/a Inhousepharmacy.co.uk; Stop4Rx; Rx Mex-Com, S.A. de C.V.; www.Nudewfds.info; Budget Medicines Pty Ltd.; Generic Cialis Pharmacy; Cutprice Pills; Allpills.us; and Pharmacy4Us.us. *See* ALJ Order No.10 at 2.

[2] ALJ Order No. 10 at 2.

[3] *Id.* at 3.

issuing a general exclusion order set forth in section 337(d)(2) and in *Certain Airless Paint Spray Pumps and Components Thereof*, Inv. No. 337-TA-90, Comm'n Opinion (Nov. 1981) ("*Spray Pumps*") were present in this case.[4] In particular, he noted the positions of Lilly and the IA that Cialis is a popular drug; infringers offer tadalafil compositions over the Internet at significantly lower prices than Lilly, often not requiring a prescription; and it is not difficult for foreign entities to gain access to the U.S. market through Internet sales.[5] Concerning circumvention, the ALJ noted that infringers operate through the Internet with little contact information, making it difficult to take effective action against individual suppliers.[6] The ALJ concluded that the considerations in this investigation are similar to those found in *Certain Sildenafil or Any Pharmaceutically Acceptable Salt Thereof, such as Sildenafil Citrate and Products Containing Same*, Inv. No. 337-TA-489, where the Commission found a general exclusion order to be appropriate.[7] Based on these considerations, he found that the *Spray Pumps* factors were satisfied and that a general exclusion order was warranted. [8]

2. Lilly's Position Before the Commission

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[4] *Id*. The Commission has determined that the statutory standards in section 337(d)(2) do not differ significantly from the standards that the Commission set forth in *Spray Pumps*. *Certain Neodymium-Iron-Boron Magnets, Magnet Alloys, and Articles Containing Same*, Inv. No. 337-TA-372, Commission Opinion on Remedy, the Public Interest, and Bonding at 5 (USITC Pub. No. 2964 (1996)).

[5] Order No. 10 at 9.

[6] *Id*.

[7] *Id*.

[8] *Id*.

Lilly argues that a general exclusion order is the appropriate remedy in this case, noting that the Commission has the authority to issue a general exclusion order under section 337(g)(2), where, as here, no person appears to contest the investigation.[9] Lilly argues that a general exclusion order is appropriate under the two factors set forth in *Spray Pumps, i.e.*: (1) "a widespread pattern of unauthorized use of the patented invention, and (2) certain business conditions from which one might reasonably infer that foreign manufacturers other than respondents to the investigation may attempt to enter the U.S. market with infringing articles."[10]

Lilly notes that the Commission has found the following two factors relevant to showing a "widespread pattern of unauthorized use:" (1) "a determination of unauthorized importation into the United States of infringing articles by numerous foreign manufacturers; and (2) other evidence which demonstrates a history of unauthorized foreign use of the patented invention."[11] In this investigation, Lilly argues that "a number of entities in India manufacture tadalafil,"[12] and provides Exhibit No. 28 illustrating that fact. Moreover, Lilly argues that "a cursory search of the internet" reveals the widespread availability of infringing tadalafil, and, consequently, there is a widespread pattern of unauthorized use.[13]

Next, Lilly maintains that the second prong of the *Spray Pumps* test - "certain business

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[9] Lilly Br. at 5.

[10] *Id*. (quoting *Spray Pumps* at 17-18).

[11] *Id*., citing *Spray Pumps* at 18-19.

[12] *Id*. at 7.

[13] *Id*. at 8.

conditions" - is also satisfied. Lilly notes that this prong includes consideration of factors such as: (1) an established market for the patented product in the U.S. market and conditions of the world market; and (2) the availability of marketing and distribution networks in the United States for potential foreign manufacturers.[14] Regarding the "established market" prong, Lilly maintains that as many as one-third to one-half of men aged 40 and older suffer from some sort of erectile dysfunction.[15] Lilly states that its global sales of Cialis® were approximately $203.3 million in 2003, and approximately $552.3 million in 2004. Thus, Lilly maintains that Cialis® is "fast becoming one of the most recognized pharmaceutical brands in the world."[16]

Lilly states that because defaulting respondents (and other infringing entities) do not bear the same research and development costs as Lilly does, those entities can offer copies of Cialis® at significantly lower prices.[17] Moreover, Lilly states that the defaulting respondents have easy access to the United States market via the Internet, making it difficult to identify and shut down these infringing suppliers.[18] Thus, Lilly maintains that a general exclusion order is necessary to

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[14] *Id*. at 7 citing *Spray Pumps*, at 19.

[15] *Id*. at 8. Lilly maintains that approximately 30 million male adults in the U.S. suffer from some degree of erectile dysfunction. *Id*.

[16] *Id*.

[17] *Id*. at 8-9.

[18] *Id*. at 9-10. For example, Lilly states that it could not serve the non-defaulting respondent in this case because it could not obtain a valid address for the company. Lilly submits that it is unclear whether that respondent still imports infringing products into the US. *Id*. at 10.

prevent infringement of its patent.[19]

Lilly proposes that several novel provisions should be added to the Commission's standard general exclusion order.[20] These provisions are summarized below:

1. Lilly will make reasonable efforts to monitor and periodically provide the Commission with reports identifying entities it believes to be engaged in the importation, sale for importation, or sale in the United States after importation of the infringing products, based upon evidence that such entities have (1) offered such products for sale on an Internet website either specifically for import into the United States or without geographical restrictions; and (2) accepted orders for such products via the Internet for shipping to addresses in the United States. Lilly, however, will not be required to provide any information regarding any website, company, or persons that Lilly is aware of, or believes to be, the subject of a separate, non-public law enforcement investigation.

2. Upon receipt of such information from Lilly, the Commission will send the identified parties a letter providing specific notification of the general exclusion order and requesting that, to facilitate U.S. Customs enforcement of the order, the identified party post within seven days a recommended disclaimer in a conspicuous location on their website in close proximity to where the tadalafil product is being advertised, offered, or sold, stating that it is unlawful to import products containing tadalafil to the United States. Under this provision, failure to post the disclaimer may be deemed by Customs to be a reasonable indication of an attempt to foster importation of articles excluded under the terms of the general exclusion order.

3. The Commission will provide copies of its letter to any third party payment facilitator (*e.g.*, Visa, MasterCard, American Express, Discover, Paypal) specifically appearing on the identified party's website, to Lilly ICOS, and to the U.S. Bureau of Customs and Border Protection (Customs), the Food & Drug Administration, and the Department of Justice.[21]

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[19] *Id.* at 10.

[20] *See Id.* at 12-13.

[21] *See also* Lilly Proposed Order at 2-3.

Lilly argues that the additional provisions are necessary to encourage voluntary compliance with the general exclusion order and to facilitate monitoring of the order by Customs and Lilly.[22]

3. The IA's Position before the Commission

Although the IA agrees that a general exclusion order is the appropriate remedy in this investigation, he recommends against the inclusion of Lilly's proposed additional provisions and contends that the Commission's standard general exclusion order provisions are sufficient to protect Lilly. The IA recommends against the inclusion of Lilly's novel provisions for several reasons. First, he argues that the additional provisions might interfere with Customs' authority and discretion in enforcing the general exclusion order.[23] He notes that Customs has the responsibility to enforce section 337 general exclusion orders, and the Commission's exclusion orders normally do not establish specific procedures for that enforcement.[24] Indeed, he noted that the Commission has repeatedly stated that enforcement of a general exclusion order is the responsibility of Customs. *See Certain Lens-Fitted Film Packages* at 11 (find that "an exclusion order is an *in rem* order, which is interpreted and enforced by the US Customs Service . . . ."); *Certain Agricultural Tractors, Lawn Tractors, Riding Lawnmowers, and Components Thereof*, Inv. No. 337-TA-486, USITC Pub. No. 3625, Comm'n Op. at 12 (August 2003) ("the enforcement of section 337 exclusion orders [is] the responsibility of Customs" . . .).[25]

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[22] Lilly Br. at 13.

[23] IA Reply Br. at 4.

[24] *Id*.

[25] *Id*.

Second, he argues that it would be more efficient if Lilly or Customs directly notified any retailer that Lilly believes is in noncompliance with the general exclusion order. He believes that having the Commission undertake such notification would add unnecessary complexity to the enforcement of the exclusion order. The IA also believes that the novel provisions proposed by Lilly would strain the Commission's already stretched resources. The IA submits that Lilly is free to solicit the voluntary support of credit card companies and other payment services to aid in enforcement of the general exclusion order.[26]

Third, the IA points out that Lilly contended in arguing for a general exclusion order that "the entities involved in the sale of infringing tadalafil into the U.S. are typically not legitimate business operations but rather "fly-by-night entities that would have no qualms about changing or obscuring their identities in order to evade a limited exclusion order." [27] The IA reasons that such "fly-by-night entities" would be no more likely to comply with a letter from the Commission than with a notification from Customs.[28]

Finally, the IA is troubled by the provision that a failure to post a disclaimer within seven days after receipt of a Commission letter would give rise to a presumption that the entity intended to foster importation of infringing articles. In the IA's view such a presumption may

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[26] *Id*. at 6. The IA supports his statement by citing Exhibit 5 to Lilly's brief, Written Statement of Mark MacCarthy on Behalf of Visa, U.S.A. Before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives (December 13, 2005) at 3 ("When alerted that specific Internet pharmacies may be accepting Visa cards for illicit transactions, Visa has worked with its member financial institutions to investigate these pharmacies and to terminate the acceptance of Visa cards for illicit activities.")

[27] IA's Reply brief at 7, citing Lilly's brief at 9-10.

[28] IA's Reply brief at 7-8.

raise due process issues.

4. Lilly's Surreply

In its surreply, Lilly argues that because the IA raised new objections to several provisions in Lilly's proposed order, its surreply should be accepted by the Commission even though the Commission's notice did not provide for such surreplies. Lilly's surreply addresses the IA's statement that one of Lilly's provisions may raise due process concerns, and Lilly's disagreement with the IA's contentions that the additional measures would be both ineffective and unduly burdensome for the Commission and Customs to administer. We grant the motion to file the surreply. However, as discussed below, we do not find Lilly's arguments persuasive.

4. Analysis

We agree with the ALJ that a general exclusion order is the appropriate remedy in this investigation and that the same considerations apply here that applied in the *Sildenafil* investigation. We also agree with the IA that Lilly's novel provisions should not be included in the Commission's order. Lilly's novel provisions call for Lilly to notify the Commission when Lilly believes that defaulting respondents or other entities are violating the general exclusion order. The Commission would then in turn notify each website of the general exclusion order and notify Customs about the offending website. We agree with the IA that such a procedure is neither "necessary [n]or appropriate" to secure compliance with the general exclusion order.[29] If Lilly believes that a particular entity has circumvented the general exclusion order, Lilly itself could notify Customs and/or the particular entity. There is no basis for Commission involvement

[29] *Id.* at 5.

at this level of the enforcement process. Commission involvement in this manner would unnecessarily add an additional party to the procedure and interfere with Customs' enforcement process. Moreover, because enforcement of a general exclusion order is the responsibility of Customs, any concerns regarding enforcement should be directed to Customs in the first instance.

We also agree with the IA that it is unclear how the additional provisions would facilitate the enforcement process.[30] There is no reason to assume that a letter from the Commission would be more effective than a notification from Customs in preventing violations of the general exclusion order. Finally, we agree with the IA that the novel provisions proposed by Lilly would be unduly burdensome for the Commission.

The Commission has broad discretion in fashioning remedies under section 337. *Viscofan, S.A. v. United States Int'l Trade Comm'n*, 787 F.2d 544, 548 (Fed. Cir.1986)("the Commission has broad discretion in selecting the form, scope, and extent of the remedy, and judicial review of its choice of remedy necessarily is limited."). In our view, there are sufficient reasons to decline to adopt Lilly's novel provisions without considering the due process issues raised by the IA.

B. Bonding

The ALJ recommended that bond provided for during the period of Presidential review, 19 U.S.C. § 1337(j), be set in the amount of 100 percent of entered value. The ALJ found that there was only limited evidence of the prices charged by defaulting respondents because they did

[30] *See Id*. at 7.

not participate in the investigation. He further found that the evidence that did exist demonstrated a wide range of prices charged by the respondents, and that respondents' prices generally were well below the retail price charged for Lilly's Cialis® product. He found that under *Certain Oscillating Sprinklers, Sprinkler Components, and Nozzles*, Inv. No. 337-TA-448 (Limited Exclusion Order March 2002), the appropriate bond in such circumstances is 100 percent of entered value.

The IA and Lilly support the ALJ's bond recommendation, and we see no reason to reject it. Accordingly, we set the bond during the period of Presidential review at 100 percent of entered value.

C. The Public Interest

Prior to issuing relief pursuant to section 337, the Commission is required to consider the effect of such relief on "the public health and welfare, competitive conditions in the U.S. economy, the production of like or directly competitive articles in the United States, and United States consumers." 19 U.S.C. § 1337(d).

Lilly argues that protection of intellectual property rights is an important public interest. It also maintains that it can meet the domestic consumer demand for tadalafil if infringing imports disappear from the U.S. market. Moreover, Lilly argues that a general exclusion is actually in the public interest because unapproved tadalafil products pose a potential risk to the public health, whereas Lilly's product has been proven to be safe and effective and is produced only in facilities that are approved by the Food and Drug Administration. The IA makes essentially the same arguments. We agree that there are no public interest considerations here

that would prevent the issuance of a general exclusion order in this investigation.[31]

By order of the Commission.

Marilyn R. Abbott
Secretary to the Commission

Issued: June 16, 2006

[31] The Commission has denied relief based on its consideration of the public interest factors in only three case, *i.e.*, *Automatic Crankpin Grinders*, Inv. No. 337-TA-60 (1978); *Inclined Field Acceleration Tubes*, Inv. No. 337-TA-67 (1980); and *Fluidized Supporting Apparatus*, Inv. No. 337-TA-182/188 (1984). In all of these cases, the domestic industry could not adequately supply the U.S. market.